

United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------------|----------------------|---------------------------------------|------------------|
| 10/801,544 | 03/17/2004 | Kazuhisa Fukushima | 042187 | 2323 |
| 38834 7590 04/26/2007 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW | | | · EXAMINER | |
| | | | SISSON, BRADLEY L | |
| SUITE 700 WASHINGTON, DC 20036 | | | ART UNIT | PAPER NUMBER |
| | | | 1634 | |
| | | <u> </u> | · · · · · · · · · · · · · · · · · · · | |
| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE . | |
| 3 MOI | NTHS | 04/26/2007 | 007 PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|
| | 10/801,544 | FUKUSHIMA, KAZUHISA | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Bradley L. Sisson | 1634 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 09 Fe | <u>ebruary 2007</u> . | | | | | |
| 2a)⊠ This action is FINAL . 2b)□ This | This action is FINAL . 2b) ☐ This action is non-final. | | | | | |
| 3) Since this application is in condition for allowar | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 53 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-11</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) <u>4-6 and 9-11</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-3,7 and 8</u> is/are rejected. | 6)⊠ Claim(s) <u>1-3,7 and 8</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | ')☐ Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine | г | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign a)⊠ All b)□ Some * c)□ None of: | priority under 35 U.S.C. § 119(a) |)-(d) or (f). | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| Copies of the certified copies of the prior | rity documents have been receive | ed in this National Stage | | | | |
| application from the International Bureau | , , , , | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | • | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application Other: | | | | | | |

DETAILED ACTION

Election/Restrictions

1. Claims 4-6 and 9-11 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 02 August 2006.

Specification

2. The objections to the specification, including the title, have been withdrawn in view of the amendments to same.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. As presently worded, claim 2 requires the movement of "other biopolymers" from a first solution through a partition and into a second solution; and the method also requires the movement of target biopolymers from the same first solution, into the same partition, and then into a third solution. It is unclear if the second and third solutions can be the same or whether or

Application/Control Number: 10/801,544 Page 3

Art Unit: 1634

not there is a material difference between them. It is also unclear if the "other biopolymers" also move into the third solution when, for example, they both have the same size/mass/charge.

6. Claim 3, w3hich depends from claim 2, fails to overcome this issue and is similarly rejected.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Application/Control Number: 10/801,544

Art Unit: 1634

10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 5,009,759 (Serwer et al.).

- 11. For purposes of examination, the term "solution" has been construed to encompass solution, regardless of viscosity. As such, the term has been construed as encompassing gels used in gel electrophoresis. The term "partition" has been construed as encompassing not only pillar arrays, filters but also gels.
- 12. Serwer et al., teaches developing and using both horizontal and vertical gels that have gradients of pore sizes. The differences in pore sizes may be abrupt or may be that found in a gradient, where an infinite number of degrees of separation can be developed. The myriad differences on pore sizes are deemed to meet the limitation of first second, and third solutions. The portions of the gradient where the target biopolymers are slower to move, and where they may eventually be trapped, are deemed to meet the limitation of applicants first and second "partition" as the target biopolymers are removed/separated/portioned from the other biopolymers.
- 13. As disclosed by Serwer et al., a mixture of biopolymers (e.g., nucleic acids or proteins) may be added/introduced into a gel, and then subjected to an electrophoretic force.
- 14. In view of the above remarks, the method of claims 1-3 is deemed disclosed, or in the alternative, rendered obvious over the disclosure of Serwer et al.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Page 4

Application/Control Number: 10/801,544 Page 5

Art Unit: 1634

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 16. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 17. Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over 6,312,910 B1 (Vellinger et al.).
- 18. Vellinger et al., column 8, disclose a method by which proteins, ligands, chemicals, antigens and other particles are isolated by multistage separation based on magnetic susceptibility and magnetophoretic mobility.
- 19. Vellinger et al., column 10, teaches of using half-cavities as well as multi-stage separation via use of multiple cavities in a sample plate assembly to aid in the separation of multiple samples of biopolymers.
- 20. The aspect of employing various magnetic fields through which biopolymers migrate, or are retained therein due to their magnetic field strengths, and the cavities or half-cavities into which the biopolymers are retained, are considered to meet the limitation of a "filter" partition as the biopolymers are filtered according to their response to magnetic fields. See column 9 and 10.
- 21. In view of the preceding remarks, the disclosure of Vellinger et al., is deemed to teach the claimed invention. If however, 6,312,910 B1 (Vellinger et al.) does not anticipate the claimed

Application/Control Number: 10/801,544 Page 6

Art Unit: 1634

invention, it would have been obvious to one of ordinary skill in the art at the time to have used the method of 6,312,910 B1 (Vellinger et al.) to isolate proteins as well as other ligands, e.g., nucleic acids, through the use of magnetophoretic mobility. In view of the detailed disclosure, and well-developed state of the art, said ordinary artisan would have had a most reasonable expectation of success.

Conclusion

- 22. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.
- Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Application/Control Number: 10/801,544

Art Unit: 1634

Any inquiry concerning this communication or earlier communications from the 25. examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

- 26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bradley L. Sisson **Primary Examiner**

Fr. L. Linon

Page 7

Art Unit 1634